## REMARKS

Claims 1-18 and 31-45 were pending. With the present Amendment, the Applicants amend Claims 1, 18, and 31-34; therefore, Claims 1-18 and 31-45 remain pending for consideration. While the Applicants do not agree with or acquiesce to the claim rejections, the Applicants have amended the aforementioned claims in an effort to expedite prosecution. The Applicants reserve the right to pursue all previous versions of all amended claims in one or more future applications.

### Claim Rejections Under 35 U.S.C. § 103

Claims 1-18 and 31-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,769,884 to Solovay in view of U.S. Patent No. 6,197,049 to Shaolian, et al. and U.S. Patent No. 6,379,382, to Yang. The Applicants respectfully traverse the rejection, as the Solovay-Shaolian-Yang combination fails to teach, suggest, or otherwise render the claims obvious.

Claims 1-17

Claim 1 recites, among other things:

> 1. An endolumenal prosthesis . . . comprising:
> a tubular wire support . . . ; and
> a uniform porous tubular ePTFE sheath on the wire support, the tubular sheath having a sheath proximal end region and a sheath distal end region, wherein the sheath is porous and configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath at the sheath proximal and distal end regions.

The applied art fails to teach, suggest, or otherwise render obvious, at least a prosthesis comprising a tubular wire support and *a uniform porous* tubular ePTFE sheath *configured to inhibit sufficient cellular ingrowth* through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath *at the sheath proximal and distal end regions*. Instead, the applied art not only fails to teach, suggest, or render such features obvious, but actually teaches away from such a combination. For example, Solovay teaches both: 1) a nonuniform porosity stent, and 2) a stent that promotes tissue ingrowth at the stent end regions.

Solovay explains that his stent has varying porosity and includes some portions that promote tissue ingrowth and other portions portions that do not. For example, at column 2, lines 3-9, Solovay explains:

> The porosity of the stent covering varies along different portions thereof. The regions of the stent covering near the ends of the stent preferably have pores to allow healthy tissue ingrowth and re-endothelialization. The middle portion of the stent covering preferably is substantially less porous than then end portions of the stent covering, or non-porous, in order to encapsulate the damaged or diseased tissue.

Indeed, Solovay explains the importance of providing portions of a covering in which tissue ingrowth occurs. For example, at column 4, lines 21-25, Solovay explains:

> What is important that, in the desired portions of the covering 30, the pores provide a lattice for tissue ingrowth allowing cells and blood vessels to travel and grow into and/or through the stent covering 30.

Solovay also explains the importance of increasing porosity in areas where healthy tissue ingrowth is desired. For example, at column 5, lines 33-40, Solovay provides:

> The important aspect is that in those areas where healthy tissue ingrowth is desired, the stent covering 30 has a higher degree of porosity and the pore diameters, and preferably also the shortest pore width, are conducive to such growth; and, in those areas where damaged tissue ingrowth is to be deterred, the stent covering 30 has a lower degree of porosity and the pore openings inhibit or prevent such growth.

Solovay clearly explains the advantages of a nonuniform stent, one of which is the "*complete* re-endothelialization of long stents". For example, at column 6, lines 30-42, Solovay provides:

> The use of a nonuniform porosity stent covering 30 provides several advantages. Unlike stent coverings having uniform porosity, the nonuniform porosity stent covering 30 can control tissue healing, response and optimize endovascular ingrowth by customizing the placement and amount, e.g. pore size and/or pore density, of porosity on the stent covering 30. Thus, the present invention promotes complete re-endothelialization of long stents and reduces the likelihood of intimal hyperplasia, rendering improved vessel patency. The porosity of the end regions 12 is adapted to permit healthy cells, capillaries, and tissue 14 to penetrate into and/or through the stent covering 30, creating and maintaining a healthy intima 55.

Therefore, for at least these reasons, the applied art fails to teach or suggest all of the language of Claim 1, or to render Claim 1 obvious. Furthermore, Solovay also explains that

unlike Claim 1, his stent and covering are designed to promote healthy tissue and capillary ingrowth near the ends of the stent. For example, at column 2, lines 12-17, Solovay explains:

> The porous portions of the stent covering promote healthy tissue and capillary ingrowth near the ends of the stent, which helps keep the stent from migrating, and promotes re-endothelialization along the entire length of the endoprosthesis implant.

Solovay also explains the preference to providing a stent coving that promotes ingrowth of healthy tissue at its end portions at column 6, lines 25-28:

> Preferably, the end portions 12 of the stent covering 30 are more porous than the middle portion 13 of the stent covering 30. As shown in FIG. 4, the more porous end portions 12 promote ingrowth of healthy tissue 14.

Again, at column 6, lines 39-42, Solovay explains that his stent permits healthy cell, capillary and tissue penetration into and/or through the stent covering at its end regions. Solovay provides:

> The porosity of the end regions 12 is adapted to permit healthy cells, capillaries, and tissue 14 to penetrate into and/or through the stent covering 30, creating and maintaining a healthy intima 55.

Therefore, even if properly combined, the Solovay-Shaolian-Yang combination also fails to teach or suggest all the language of Claim 1. The applied art subsequently must fail to render Claim 1 obvious.

In addition, Solovay, Shaolian and Yang may not be combined because the combination renders Solovay unsatisfactory for its intended purpose and because references cannot be combined where a reference teaches away from their combination. The M.P.E.P. clearly explains that a "proposed modification cannot render the prior art unsatisfactory for its intended purpose." M.P.E.P. § 2143.01(V). The M.P.E.P. also explains, "It is improper to combine references where the references teach away from their combination." M.P.E.P. § 2141.02, 2145(X)(D)(2).

Solovay as a whole (and particularly the portions mentioned above) teaches *stent coverings having sufficient porosity to permit tissue ingrowth* at least at the proximal and distal tissue-contacting portions.

Since Solovay explicitly teaches the desirability of tissue ingrowth through a stent covering at a covering's proximal and distal end regions, it would be improper to modify such teachings to render it unsatisfactory for such intended purpose. The Office Action proposes to modify Solovay in exactly this impermissible manner, which renders the combination improper.

The Office Action fails to consider the M.P.E.P. requirements provided above, namely that a "proposed modification cannot render the prior art unsatisfactory for its intended purpose" (M.P.E.P. § 2143.01) and that "It is improper to combine references where the references teach away from their combination" (M.P.E.P. §§ 2141.02, 2145).

Modifying Solovay as proposed by the Office Action (e.g., by providing a sheath that inhibits cellular ingrowth) renders Solovay unsatisfactory for its intended purpose. In addition, by emphasizing the desirability of tissue ingrowth through a stent covering at the covering's end portions, Solovay actually teaches away from the Office Action's proposed combination, as discussed above. Therefore, the Office Action has improperly combined and/or modified the applied art. As a result, the Solovay-Shaolian-Yang combination cannot render the claims obvious.

Claims 2-17 depend from Claim 1, and therefore distinguish over the applied art for at least the same reasons discussed above. In addition, Claims 2-17 distinguish over the applied art for the unique combinations of features recited in those claims.

For example, the applied art does not teach, suggest, or otherwise render obvious an ePTFE sheath having a wall thickness of no greater than about 0.2 mm (as required in Claim 2), a density of at least about 0.5 g/ml, 0.75 g/ml, or within the range of from about 1.1 to about 1.5 g/ml (as required in Claims 5-7, respectively), an average distance between ePTFE nodes within a range of from about 6 microns to about 80 microns (as required in Claims 8-10), or having a water entry pressure in the range of from about 10 psi to about 24 psi (as required in Claim 17). Therefore, Claims 2, 5-7, and 17 distinguish over the applied art for at least these additional reasons, as well.

The Office Action dismisses the language of these claims as merely optimum or workable ranges involving only routine skill in the art. However, as the Applicant's explained in the Office Action Response filed June 16, 2009, the Board of Patent Appeals and Interferences recently rejected similar conclusions in a similar situation. In Ex parte Whalen II (decided July 23, 2008), the Board explained (emphasis added), "While 'the discovery of an optimum value of a variable in a known process is normally obvious,' this is not always the case. *One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results.*" Whalen II, p. 14 (citing In re Antoine, 559 F.2d 618, 620 (C.C.P.A. 1977)).

The Office Action did not address these previously presented arguments and dismissed them as "moot in view of the new ground(s) of rejection." However, the Applicant's previous discussion of Ex parte Whalen II is relevant to the present rejection, as well. As previously discussed, the Board in Whalen II explained, "Here, the Examiner has not pointed to any teaching in the cited references, or provided any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to 'optimize' the prior art compositions by increasing their viscosity to the level recited in the claims." Id. Therefore, the Board concluded that the Examiner had not made out a prima facie case of obviousness.

The Office Action in the present Application similarly fails to provide any indication that the language of Claims 2, 5-7, and 17 are merely optimized values of parameters that have been recognized in the prior art as parameters that would affect results. Therefore, for the same reasons discussed in Whalen II, the present Office Action also fails to establish a prima facie case of obviousness of Claims 2, 5-7, and 17.

Claim 18

Claim 18 recites, among other things:

> 18. A bifurcated endolumenal prosthesis . . . comprising:
> a proximal wire support section . . . ;
> a first wire branch section at the distal end of the proximal support;
> a second wire branch section at the distal end of the proximal support; and
> a uniform porous membrane carried by the wire support section, the membrane having a membrane proximal end region and membrane distal end regions and configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions.

For similar reasons as those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising a uniform porous membrane configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions. In addition, as discussed above, the Office Action impermissibly combines the applied art.

Therefore, for at least these reasons, Claim 18 distinguishes over the applied art, as well.

Claim 31

Claim 31 recites:

> 31. A prosthetic vascular graft, comprising:
> an expandable tubular wire support;
> a uniform porous, tubular ePTFE layer carried by the support, the ePTFE layer having:
> a wall thickness of less than about 0.15 millimeters;
> an average density of greater than about 0.75 grams per milliliter; and
> an average distance between nodes in the range of between about 6 to about 80 microns;
> so that the uniform porous ePTFE layer prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length, which are in contact with a vessel wall.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a graft comprising a uniform porous, ePTFE layer that prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length, which are in contact with a vessel wall. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 31 relating to wall thickness, average density, and average distance between nodes as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 31 at least because it fails to indicate where the allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 31 distinguishes over the applied art, as well.

Claim 32

Claim 32 recites, among other things:

> 32. An artificial vascular prosthesis comprising an enlargeable support structure having an expanded, uniform porous, polytetrafluoroethylene layer thereon, the layer having a microstructure consisting of nodes interconnected by fibrils which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm, in which either the density is greater than about 1 gram per milliliter or the wall thickness is less than about 0.2 millimeters, or both.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising an expanded, uniform porous, polytetrafluoroethylene layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 32 relating to density and wall thickness as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 32 at least because it fails to indicate where the allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 32 distinguishes over the applied art, as well.

Claim 33

Claim 33 recites, among other things:

> 33. A method of treating a patient, comprising:
> providing an implantable tubular prosthesis, having a uniform porous ePTFE layer thereon . . . ;
> positioning the prosthesis across a defect . . . ; and
> inhibiting formation of a viable neointima on a second side of the layer throughout the contacting portion, nourished through the layer;
> wherein the inhibiting step comprises providing the ePTFE layer with a density of greater than about 0.75 grams per milliliter and a wall thickness of less than 0.2 mm.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a method of treating a patient comprising providing prosthesis having a uniform porous ePTFE layer thereon and inhibiting the formation of a viable neointimal on a second side of the layer throughout the contacting portion, nourished through the layer. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 33 relating to density and wall thickness as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 33 at least because it fails to indicate where the allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 33 distinguishes over the applied art, as well.

Claims 34-45

Claim 34 has been amended to recite, among other things:

> 34. An endolumenal prosthesis . . . comprising:
> a tubular wire support . . .; and
> a uniform porous, tubular ePTFE sheath on the wire support, the porous, tubular sheath having a proximal end and a distal end and being configured to have a water entry pressure of at least about 10 psi, and wherein the uniform porous tubular sheath is configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising a uniform porous, tubular ePTFE sheath on a wire support configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 34 relating to water entry pressure as merely an optimized parameter. The Office Action fails to establish a prima facie case of obviousness of Claim 34 at least because it fails to indicate where the allegedly optimized parameter was recognized in the prior art as a parameter that would affect results.

Therefore, for at least these reasons, Claim 34 distinguishes over the applied art, as well. Claims 35-45 depend from Claim 34, and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 35-45 distinguish over the applied art for the unique combinations of features recited in those claims.

**No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior

prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

## CONCLUSION

In view of the foregoing amendments and remarks, the Applicants submit that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call the Applicants' counsel at the number indicated below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 15, 2010

By: /Andrew I. Kimmel/
Andrew I. Kimmel
Registration No. 58,855
Attorney of Record
Customer No. 20995
(949) 760-0404

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